

Appointment

From: Wozniak, Chris [wozniak.chris@epa.gov]
Sent: 2/2/2017 9:04:02 PM
To: Wozniak, Chris [wozniak.chris@epa.gov]; Kough, John [Kough.John@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; McNally, Robert [Mcnally.Robert@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Wakefield, Benjamin J. [wakefield.benjamin@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Wyatt, TJ [Wyatt.Tj@epa.gov]; laura.epstein@fda.hhs.gov; Brinda.Dass@fda.hhs.gov; Reynolds, Alan [Reynolds.Alan@epa.gov]; Tapken, Wiebke [Tapken.Wiebke@epa.gov]; Maignan, Tawanda [Maignan.Tawanda@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Saunders, Jennifer [Saunders.Jennifer@epa.gov]; Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Ciarlo, Timothy [Ciarlo.Timothy@epa.gov]
CC: Kausch, Jeannine [Kausch.Jeannine@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]
Subject: OPP / Oxitec / FDA meeting
Location: DCRoomPYS8100/Potomac-Yard-One
Start: 2/9/2017 8:00:00 PM
End: 2/9/2017 9:30:00 PM
Show Time As: Tentative

Jack Bobo (Intrexon) and Camilla Beech (consultant for Oxitec) will be coming in to discuss the possibilities for regulatory oversight of their *Aedes aegypti* OX513A sterile male mosquitoes. As you know, a major portion of the discussion will center around the transition from FDA-CVM for oversight by OPP, as well as exploring requirements / timing for an EUP or Section 18 action.

Likely the Intrexon contingent will grow and I will forward names and an agenda as they become available. FDA-CVM personnel to attend include Laura Epstein and Brinda Dass.

I am adding in Mark Suarez from RD for his perspective on mosquito control and TJ Wyatt for any questions which may arise from talk of a Section 18 action. Intrexon has indicated that this is one area they would like to explore.

FDA's site has information and links to Draft Guidance document #236 on oversight of GE mosquitoes as well as links to the EA and FONSI produced for the OX513A product.

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm446529.htm>

Chris

Ex. 6 - Personal Privacy
Code: Ex. 6 - Personal Privacy